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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,794	PAULETTI ET AL.	
	Examiner	Art Unit	
	Charlesworth Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 8/13/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Applicant's statement that no new matter is added by the amendment is acknowledged and made of record. Applicant's statements regarding where support can be found for the claim amendments as delineated on page 9 of the applicant's Response to Office action, mailed 5/10/07, are acknowledged and made of record (see below):

Claim 47 is supported in the specification page 1, lines 20-24(1:20-24) and 1:32-36 for solid, semi-solid or liquid foam or film devices, 2:1-12 for non-film or non-foam devices made of different material, 23:30-35 and page 24:1-35, for polymers.

Claim 48 is supported on page 33, lines 2-10.

Claim 49 is supported on page 33, lines 11-36, page 34 and page 35, lines 1-11.

Claim 50 is supported on page 7, lines 19-27.

Claim 51 is supported on page 23, lines 30-35 and page 24.

Claim 52 is supported on page 25 and 26, Table 1.

Claim 53 is supported on page 5, lines 30-36.

Claim 54 is supported on page 26, lines 16-32 for mucoadhesive agents, page 27, lines 15-36, pages 28-30, for penetration enhancers, page 30, lines 236 and page 31, lines 1-10 for release modifiers.

Claim 55 is supported on page 26, lines 7-15.

Claim 56 is supported on page 22, lines 15-33.

Claim 57 is supported on page 7, lines 19- 27

Claim 58 is supported on page 12, lines 27-31.

This action is made final, which is necessitated by the claim amendment narrowing the scope of invention, for example, by the recitation of the limitation *"wherein said foam or film device is preformed into a solid or semi-solid foam tampon ....or is a liquid bead or a single or double sided foam or film sheet, ..."* as recited in claim 47.

Status of the Claims

New claims 47-58 are currently pending in this application.

Claims 1-46 are cancelled.

Restriction Requirement

The restriction requirement mailed 12/21/06 is withdrawn (see pages 2-4). The election of species requirement as of record is maintained.

Terminal Disclaimer

Receipt of the terminal disclaimers in response to the ODP rejections based on US Patent 6,982,091 ('091 patent), US Patent 6,086,909 ('909 patent), and copending applications 10/335,759, 11/126,863; 11/208,209; 11/180,076; and 11/522,126 are acknowledged and made of record.

Declaration under 37 CFR 1.130

Receipt of the signed declaration of Richard J. D'Augustine dated August 10, 2007, declaring common ownership of the instant claimed subject matter and US Patent 6,905,701, US Patent 6,086,909 at the time the later invention was made, has been considered and made of record.

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

It does not include the notary's seal and venue.

Besides, a declaration filed under 37 CFR 1.130 is insufficient to overcome the 102(b) rejection with respect to US patent 6,086,909 (see Office action mailed 5/10/07, pages 7-9).

Response to applicant's arguments/remarks

Rejection under 112, 2nd para

This rejection is withdrawn in view of applicant's cancellation of claim 46.

Nonstatutory obviousness-type double patenting (ODP) rejections

The ODP rejection based on copending of US Patent Application No. 10/654,145 is withdrawn as this application is now abandoned.

The other ODP rejections of record (Office action mailed 5/10/07, pages 4-6) are maintained as the above referenced terminal disclaimers have not been approved. Upon the approval of said terminal disclaimers, the corresponding ODP rejections will be withdrawn.

Rejection under 102(b)

Applicant contends that Harrison et al. ('909 patent) do not teach all the limitations set forth in the instant claimed invention for the following reasons:

1) Harrison et al. do not teach the following features in the same combination and for the same use. Specifically, the new claims are directed to a foam or film device that is a stand alone device made of specifically identified substrate polymers in combination with a therapeutically effective agent for topical delivery of a therapeutically effective agent to a vaginal, nasal, buccal, scrotal or labial epithelium, wherein the device is prepared from a composition comprising at least one substrate polymer and the therapeutically effective agent , and further wherein the foam or film device is preformed into a solid or semi-solid foam tampon, foam tablet, foam cyclinder, foam or film strip, foam or film pad, foam or film pillow, foam or film tube, foam or film sheet, foam or film sphere, foam or film ring, foam bead or a single or double sided foam or film sheet, or is a liquid preparation that forms a foam or film layer device upon contact with an epithelial tissue or with a surface of non-foam or non-film device made of different material (see applicant's Response to the Office action, received 8/13/07, at page 15, full paragraphs 1-4). Harrison et al. only discloses delivery to and through the vaginal mucosa to the

uterus and to treatment of dysmenorrhea; Harrison et al. do not disclose the polymers used for preparation of the foams or films as claimed in the instant claims nor is it directed to treatment of dysmenorrheal.

2) Harrison is a co-inventor of the '909 patent, which is co-owned by the same assignee.

In response, this rejection is maintained as applicant's arguments, claim amendment, and declaration are not found to be sufficient to overcome the rejection for the reasons previously made of record in the Office action mailed 5/10/07 (pages 7-9) and the additional reasons set forth below:

i) The instant claimed limitations clearly overlap with the teaching of Harrison et al. For example, Harrison et al. teach drug delivery systems in the form of tampon-like devices, vaginal ring, foam, vaginal sponge etc (col. 1, lines 13-16 and col. 9, lines 5-67); instant claim 47 is directed towards a foam or film device for topical delivery of a therapeutically effective agent to a vaginal, nasal, buccal, scrotal or labial epithelium. Harrison et al. teach a controlled release drug delivery system comprising non-limiting biocompatible excipient for applying the an active agent, including a lipohilic carrier or a hydrophilic carrier e.g. polyethylene glycol; muco-adhesive agents such as alginate and pectin; and penetration enhancers (col. 2, third full para). Polyethylene glycol is a film-forming polymer as evidenced by the teaching of Samour et al. (US Patent 5,807,957, see especially col. 18, Examples 4-6).

Samour et al. (US Patent 5,807,957) teach lipophilic or amphiphilic or hydrophilic film-forming polymers for use individually or in combination as a delivery system for

delivering pharmacological or cosmetic agents to the skin or hair; the disclosed film-forming amphilic polymers include: polyethylene glycol methyl ether, polyethylene glycol butyl ether, ethoxyethoxyehtanol, polyethylene glycol, methylenedicyclohexy, methylenedicycloheyxl and hexamethylene (abstract; col. 17, lines 9-51, and col. 1, line 56 to col. 19, line 10, including Examples 1-8). Samour et al. teach compositions comprising suitable penetration enhancers to facilitate penetration through the stratum corneum and epidermis layers into and through the dermal layer and blood stream in combination with pharmacological dermatological agents and the film-forming polymer is also taught (col. 17, lines 9-51).

Rejections under 103(a)

Applicant contends that this rejection based on Harrison ('909 patent), in view of Yang (US Patent 6,316,019), in view of Durrani et al. (US Patent 6,159,491), in view of Pauletti et al. (US Patent 6,905,701) should be withdrawn the reasons stated above regarding the '909 patent (in connection with the rejection under 102(b)) and for the following additional reasons:

1) Like Harrison et al., Pauletti et al. (6,905,701) is disqualified as being the same inventor and commonly co-owned.

2) Durani discloses a gel and there is no gel claimed in the instant claims.

3) Yang is directed towards preparation of tampons.

4) A prima facie case of obviousness is not met in view of the two references being disqualified i.e. the combination of Yang and Durani does not render the instant invention obvious.

This rejection is withdrawn.

REJECTIONS

Nonstatutory Obviousness-Type Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 47-58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-27 of US Patent 6,905,701 B2 ('701). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims.

In particular, claim 24 of '701 is directed towards a medicated intraviginal device for a transmucosal delivery of bisphosphonates to the general circulation. In view of the fact that the treatment populations overlap, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant invention with a reasonable expectation of success.

Thus, claims 29-46 are deemed obvious variants of the limitations of the patented subject matter claimed in '701.

For the same reasons stated above, claims 29-46 are similarly deemed to be obvious variants of the limitations of the patented subject matter of claims 21-33 of U.S. Patent 6,982,091 ('091).

In addition, claims 29-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the following: claims 49-54, 55, 57-79 of copending Application No. 10/335,759; claims 1-15 of copending Application No. 11/126,863, claims 45-53 of copending Application No.

11/208,209, claims 1-55 of copending Application No. 11/180,076, and claims 20-23 of copending Application No. 11/522,126, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of each other for essentially the same reasons stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims of the copending applications have not in fact been patented.

These rejections are being maintained because the corresponding terminal disclaimers have not been approved.

Claim rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47-58 are rejected under 35 USC 102(b) as being anticipated by Harrison et al. (US Patent 6,086,909).

The above discussion in connection with the Response to applicant's arguments/remarks regarding the rejection under 102(b) is incorporated by reference. Harrison et al. (6,086,909) teach devices, compositions and methods for treating dysmenorrheal by intravaginal administration of therapeutic and/or palliative drugs to the uterus (column 1, lines 13-16). Harrison et al. teach controlled release drug delivery system in the form of, for example, a tampon-like device, vaginal ring, pessary, tablet,

paste, suppository, vaginal sponge, bioadhesive tablet, bioadheisve microparticles, cream, lotion, foam, ointment, or gel (column 9, lines 5-67). Harrison et al. teach various tampon like devices which can be used to deliver drugs for the treatment of dysmenorrheal wherein the drug is incorporated into the device via numerous methods (column 9, lines 29-34). Claim 47 recites the term *"[a] foam or film device for topical delivery of a therapeutically effective agent to a vaginal, nasal, buccal, scrotal or labial epithelium."* Harrison et al. teach that the active drug can be incorporated into a gel-like bioadhesive reservoir in the tip of the device, or the drug can be in the form of a powdered material positioned at the tip of the tampon, or the drug can also be dissolved in a coating material which is applied to the tip of the tampon, or the drug can be incorporated into an insertable suppository which is placed in association with the tip of the tampon (column 9, lines 36-45). Claim 47 recites the term "a foam or film pad," "a foam or film strip," " a solid or semi-solid foam tampon;" claim 50 recites the term "conventional tampon, ring, strip, pad, pillow, sheet, tube, sphere;" claim 55 recites the term "said composition further comprises a therapeutically acceptable additive or excipeint, wherein said additive or excipient is a solubilizing agent, buffering agent, filler, preservative, plasticizer, surfactant or anti-oxidant; " claim 56 recites the term "a single layer or multiple layers of a single or double-sided sheet;" claim 57 recites the term "wherein said therapeutically effective agent is incorporated into or attached to one side or both sides of the film;" claim 58 recites the term "wherein said therapeutically effective agent is incorporated into said foam before the foam formation or be coated on the inner pores of prefabricated foam" which given their broadest reasonable

possible interpretation clearly overlaps with the teaching of Harrison et al. Harrison et al. teach a controlled release drug delivery system comprising non-limiting biocompatible excipient for applying the an active agent, including a lipohilic carrier or a hydrophilic carrier e.g. polyethylene glycol; muco-adhesive agents such as alginate and pectin; and penetration enhancers (col. 2, third full para). Polyethylene glycol is a film-forming polymer as evidenced by the teaching of Samour et al. (US Patent 5,807,957, see especially col. 18, Examples 4-6). Claim 47 recites the terms "polyethylene glycol," "collagen," pectin," "alginic acid;" claim 51 recites the term "polyethylene glycol;" claim 52 recites the term "said composition further comprises a penetration enhancer, ... mucoadheisve agent, hydrophilic or hydrophobic release modifier;" which also overlap with the teaching of Harrison. In Figure 6, the tampon device includes a distal porous foam section, which is preferably a soft, light weight, physiologically inert foam material of polyurethane, polyester, polyether, or other material such as collagen (column 10, lines 28-40). In one aspect, the invention provides a method for treating a human female suffering from dysmenorrheal comprising contacting the vaginal epithelium of the female with a pharmaceutical agent selected from the group consisting of nonsteroidal anti-inflammatory drugs, anti-prostaglandins, prostaglandin inhibitors, COX-2 inhibitors, local anesthetics, calcium channel blockers, potassium channel blockers (column 1, line 66 to column 2, line 16). Claim 48 recites the term "non-steroidal anti-inflammatory agent," "anti-osteoporosis agent," "anti-HIV agent;" claim 49 recites the term "COX-2 or COX-1 inhibitor agent;" Harrison et al. teach that non-limiting examples of nonsteroidal

anti-inflammatory drugs suitable for practice of the invention includes ketorolac (column 2, lines 17-21); see also Example 4 at columns 16-18).

Harrison et al. disclose methods for combining the pharmaceutical agent with a drug delivery system for intravaginal delivery of the agent; drug delivery system include a tampon device, vaginal ring, pessary, tablet, vaginal suppository, vaginal sponge, bioadhesive tablet, bioadhesive microparticle, cream, lotion, foam, ointment, solution and gel (column 2, second full paragraph). In one embodiment, a tampon device is sheathed in a thin, supple, non-porous material such as a plastic film or a coated gauze that surrounds the absorbent tampon material like a skirt and opens like an umbrella when it comes in contact with the vaginal environment (column 3, lines 55-67).

Harrison et al. teach a controlled release drug delivery system comprising non-limiting biocompatible excipient for applying the agent including a lipophilic carrier or a hydrophilic carrier e.g. polyethylene glycol; muco-adhesive agents such as alginate and pectin; and penetration enhancers e.g. bile salts, organic solvents, ethoxydiglycol, or interesterified stone oil (column 2, third full paragraph). In certain embodiments, the excipent comprises between about 60 to 90% by weight lipohilic carrier, between about 5 to 25% mucoadhesive agent, and between abut 5 to 20% penetration enhancer (column 2, lines 60-67). In another embodiment, the formulation comprise between about 5-20% sorption promoter (column 8, lines 31-34). Claim 54 recites the term *"wherein said penetration enhancer is present in amount from about 0.1% to about 60%, by weight, wherein said mucoadhesive agent is present in from about 0.5% to about 10%, by weight, and wherein said release modifier is present in amount from*

about to about 5% to about 70%, by weight." Thus, the claimed invention is anticipated by Harrison et al. because the limitations of the instant invention overlaps with Harrison et al. for the reasons stated above.

Newly Applied Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 47-58 are rejected as being unpatentable over Partain III et al. (US Patent 4,946,870), in view of Igarashi (US Patent 4,997,653), in further view of Durrani (US Patent 6,159,491).

Partain III, et al. (US Patent 4,946,870) delivery systems useful for the topical delivery of pharmaceutical or therapeutic actives which can be administered to a desired **topical or mucous membrane** site of a subject, and wherein upon delivery, the systems provides a biocompatible substantive, gas permeable, **film** from which actives are available at the designated site (see especially abstract, col. 2, lines 8-26; and col. 10, lines 23-29). Partain et al. teach that the said delivery system is comprised of from about 0.01 to about 99.99 weight percent of at least one aminopolysaccharide selected from the group consisting of 1) chitosonium polymers, and 2) covalent chitosan derivatives (col. 2, lines 29-50; col. 3, line 61 to col. 4, line 61); chitosan derivatives are known in the art to be mucoadheisve or bioadhesive agents. Partain et al. teach that in many instances the delivery system comprises a chitosan derivative, an active component , one or more pharmaceutically acceptable diluents or vehicles (e.g. water, ethanol, **glycerine**, **dimethylether**, carbon dioxide, butane, **polyethylene glycol**, **ethoxylated or propyloxylated glucose**, **sorbitol derivatives**, and the like), wherein the chitosan derivative can be about 0.5 to about 30 weight percent of the system, with the remainder of the system being a diluent and optionally, other additives (col. 9, lines 22-68). Claim 55 recites the term *" wherein said composition further comprises a*

therapeutically acceptable additive or excipeint, hwerein said additive or excipient is a solubilizing agent, buffering agent, filler, preservatives, plasticizer, surfactant or anti-oxidant" reasonably overlaps with the teaching of Partain et al. additives (col. 9, lines 22-68). Claim 54 recites the term *"wherein said mucoadhesive agent is present in from about 0.5% to about 10%, by weight,"* which overlaps with the teaching of Partain et al. additives (col. 9, lines 22-68). Claim 52 recites the term *"mucoadhesive agent."* Partain et al. teach that typical sites for topical delivery include application to the dermal, ophthalmic, and mucous membranes and tissues such as the skin, eyes, ears, mouth, nose, throat, rectum, vagina and urethra (col. 1, lines 49-52). Partain et al. teach that the active/chitosan derivative mixture may be applied to the skin or mucosa in the form of a **pre-formed film**, sponge, powder, or other composites (col. 3, lines 20-52; and col. 10, lines 23-29). Instant claim 47 recites the term *"wherein said foam or film device is preformed into a solid or semi-solid tampon, foam tablet, foam cylinder, foam or film strip, foam or film pad, foam or film pillow, foam or film tube, foam or film sheet, foam or film sphere, foam or film ring, foam bead or a single or double sided foam or film sheet, or is a liquid preparation that forms a foam or film layer device upon contact with an epithelial tissue or with a surface of non-foam or non-film device made of different material."* Claim 50 recites the terms "tampon, ...ring, strip, sheet, tube, ..." which overlaps with the teaching of Partain et al. (col. 3, lines 20-52). Claim 58 recites the term *"wherein said therapeutically effective agent is incorporated into said foam before the foam formation or be coated on the inner pores of prefabricated foam"* Partain et al. teaches that chitosan derivatives are good humectants; the humectant properties

enhance the absorption of the actives into the tissues (col. 3, lines 53-60). Partain et al. teach many pharmaceutical and therapeutic actives, including anti-inflammatory analgesics (e.g. salicyclic acid, diflunisal, acetaminophen, sulindac, ibuprofen, ketoprofen, naproxen), local anesthetics, antibiotics (e.g. erythromycin, clindamycin), antiviral agents (e.g. acyclovir), antifungal agents (e.g. miconazole), calcium channel blockers (e.g. diltiazem), vasodilators (e.g. nitroglycerine), and autacoids (e.g. oxytocin, vasopressin, leukotrienes, endorphins, and other pharmaceutically active peptides) wherein the concentration of the actives in the delivery system vary from as little as 0.0001 up t 5 percent or higher, by weight of the delivery system (col. 8, line 7 to col. 9, lines 45-48). Claim 48 recites the term *"non-steroidal anti-inflammatory agent, vasodilatory agent, calcium channel anagonists agent, local anesthetic agent, antimicrobial agent ...;"* claim 49 recites the terms *"naproxen," diltiazem, nitroglycerin, miconazole, acyclovir, oxytocin,"* for example. Partain et al. teach that additives for the **enhanced percutaneous absorption** of various pharmaceutical or therapeutic actives include **propylene glycol, glycerol**, urea, diethyl sebecate, sodium lauryl sulfate, sodium laureth sulfate, sorbitan ethoxylates, nicontinate esters, oleic acid, pyrrolidone carboylate esters, N-methyl pyrrolidone); a wide variety of other actives can be employed either alone or in combination (col. 9, lines 22-39). Claim 53 recites penetration enhancers e.g. *propylene glycol and glycerol;* claim 51 recites the term *"polyethylene glycol."* Partain et al. exemplify **mineral oil** (see col. 10, line 54 to col. 11, line 24). Claim 53 recites the term *"mineral oil"* as being an example of a release modifier. The term *"wherein said release modifier is present in amount from about to*

about 5% to about 70%, by weight," as recited in claim 54, for the purposes of this rejection, given its broadest reasonable possible interpretation is construed to overlap with the teaching of Partain et al. (see col. 10, line 54 to col. 11, line 24). The limitations recited in claims 56, 57, and 58 are reasonably construed to be coextensive characteristics of the claimed invention. Partain et al. do not Ota's ring, or collagen, or antineopalstic drugs.

Igarashi (US Patent 4,997,653) teaches T-shaped or Ota's ring-like intrauterine preparations having a **single-layer structure, or a two-layer structures in which a core** comprising a piece of Silascon Rod or other material is embedded (col. 2, lines 24-68). Igarashi teaches that preparations comprise 20 to 50 parts by weight of the active component, or danazol, 50 to 80 parts by weight of a matrix base, and optionally 0.5 to 8 parts by weight of a release-promoting agent (col. 3, lines 21-52). Claim 56 recites the term *"a single layer or multiple layers of a single or double-sided sheet,"* which is construed to be satisfied by the teaching of Igarashi (col. 2, lines 24-68). Igarashi teaches that the matrix base may be selected from various polymeric compounds including silicone rubber (polydimethylsiloxane), polymethyl methacrylate, polyhydroxy methacrylate, **polyethylene glycol**, **polyvinyl alcohol**, and **collagen**; polydimethylsiloxane, silicone-carbonate copolymer, ethylene-vinylacetate copolymer, ethylene-vivnylacetate copolymer and ethylene-vinylalcohol copolymer are the most preferred for the retention and release of danazol (col. 3, line 53 to col. 4, line 42).

Durrani (US Patent 6,159,491, **already made of record**) teach bioadhesive, prolonged release drug composition comprising a synergistic formulation of

carrageenan, acrylic acid containing **polymers**, agarose and an effective amount of a therapeutic agent (column 6, line 10-13). Durrani disclose an embodiment containing acrylic containing polymer such as polycarbophil, a homopolymer such as acryclic acid and divinyly glycol, a copolymer of acrylic acid and a selected C10 to C30 alkyl acrylate copolymer (column 6, lines 19-26). Durrani teaches that one or more of the therapeutic agents dispersed or dissolved within the bioadhesive, prolonged release drug composition may be selected from drugs, including, for example, antiinflammtory, **antineoplastic** or an analgesic agent. Durrani discloses a bioadhesive vaginal gel dosage form designed to incorporate a therapeutic agent for local or systemic action when administered intravaginally.

Based on the teaching of Partain et al. systemic administration of drugs is associated with certain undersirable effects, someone of skill in the art would have been motivated to combine the above cited prior art teachings to create the instant inventive concept.

Thus, someone of skill in the art at the time the instant invention was made would have found it obvious to create the instant claimed invention with reasonable predictability.

Claim rejections – 35 USC 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 48, 49, 53, 54 and rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites the terms "suppocire AS2X," suppocire CM, Witeposol H15, Witerpsol W25, carbopol, poloxamer," but fails to state the full generic name of these apparent brand names. It is suggested that this specific rejection may be overcome by either replacing the terms with their full generic names or, alternatively, amend the claim by inserting the full name in parenthesis at the first occurrence of the terms in the claim set. It is also noted that even though the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim 48 recites the term "anti-HIV agent" but fails to state the full meaning of the term at the first occurrence the term is recited in the claim set. This limitation is vague and indefinite because it is not clear what "anti-HIV agent" means. It is suggested that this specific rejection may be overcome by either replacing the term "anti-HIV agent" with the full name or, alternatively, amend the claim by inserting the full name in parenthesis at the first occurrence of the term "anti-HIV agent" in the claim.

Claim 49 recites the terms "COX-2 or COX-1;" "AZT;' gastrine G17," but fails to state the full meaning of the term at the first occurrence the term is recited in the claim set. This limitation is vague and indefinite because it is not clear what these terms

mean. It is suggested that this specific rejection may be overcome by either replacing the terms "COX-2 or COX-1;" "AZT;' gastrine G17," with the full name or, alternatively, amend the claim by inserting the full name in parenthesis at the first occurrence of the terms in the claim.

Claim 54 recites the term "from about to about 5% to about 70%, by weight." This claim is indefinite because it is unclear what the term means.

Relevant Art of Record

The below prior art references made of record and relied upon is considered pertinent to applicant's invention.

Samour et al. (US Patent 5,807,957) teach lipophilic or amphiphilic or hydrophilic film-forming polymers for use individually or in combination as a delivery system for delivering pharmacological or cosmetic agents to the skin or hair; the disclosed film-forming amphilic polymers include: polyethylene glycol methyl ether, polyethylene glycol butyl ether, ethoxyethoxyehtanol, polyethylene glycol, methylenedicyclohexy, methylenedicycloheyxl and hexamethylene (abstract; col. 17, lines 9-51, and col. 1, line 56 to col. 19, line 10, including Examples 1-8). Samour et al. teach compositions comprising suitable penetration enhancers to facilitate penetration through the stratum corneum and epidermis layers into and through the dermal layer and blood stream in combination with pharmacological dermatological agents and the film-forming polymer is also taught (col. 17, lines 9-51).

Jellum et al. (US Patent 7,241,460) teach skin penetration enhancing agents, including propylene glycol laurate, vpropylene glycol, alcohols (e.g. ethanol,

isopropanol, essential oils, Tween 80 and other surfactants (col. 4, lines 46-57); and bioadhesive (i.e. mucoadheisve) agents, including natural or synthetic, polyanionic, polycatuonic or neutral (col. 5, line 5 to col. 6, line 6). Jellum et al. teach that preferred bioadhesive agents include polyacrylic hydrogels, chitosan, polyvinyl alcohol, hydroxypropyl cellulose, hydroxyl propyl methyl cellulose, sodium alginate, scleroglucan, xanthum gum, pectin, Orabse and polygalactonic acid (col. 6, lines 12-15). Jellu et al. also teach polymeric bioadhesives may be crosslinked and be in the form of copolymers e.g. poly(acrylic acid) polymers (or copolymers) – a polycarbophil e.g. Carbomer (Carbopol) (col. 6, lines 1-11).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

15 November 2007
CER

BRIAN-YONG S. KWON
PRIMARY EXAMINER